B. Bull DATE CONSIDERED EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609: Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

EXAMINER

Applicant: Serial No:

John O'Connor, et al.

Filed:

09/630,215 August 1, 2000

							Snee	:1 <u></u>	U										
orm PTO	-1449				t of Commerce lemark Office	Atty. Doci		Seria	SOVE 0,215										
					CITATION	JPW/SI	IS/MVM	איטיז	9720										
I	NFORMA	TION	DISC	CLOSURE (CITATION &	Applicant	s	- NUT											
	(Use	severa	al she	ets if necess	a(X) HON 1 1 2000	John O'	Connor et al.												
	(a(Y) NOV 1 , 2000	Filing Dat		TECH CE	VTER 1800										
						August		1641)										
-					HADEMAN		1, 2000	1041											
				U.S. PA	TENT DOCUMEN	TS													
xaminer iitial	Docur	nent Nu	mber	Date	Name	Class	Subclass	Filing if App	Date ropriate										
							 												
		1	\Box																
			++																
-	+++	╅	++																
	+++		+					_											
			1_1_																
<u> </u>	ı			FOREIGN 1	PATENT DOCUM	ENTS													
ľ	Docum	ent Nu	ımbe	r Date	Country	Class	Class Subclass		slation										
								Yes	No										
	ОТ	HER D	OCUM	1ENTS (Includ	ling Author, Title, Date	e, Pertinent	Pages, Etc.)												
					Fragment, a Potent			pic Pre	gnancy										
98	1				l.Diagn.Ther. 12: 33				<u> </u>										
0-					or Down Syndrome		First and Secon												
$\sim 1/1$					ation Parameters", C	-													
$\langle \chi \chi $	HIHIMESI																		
88		alcorra	Kovalevskaya et al., (1999) "Early Pregnancy Human Chorionic Gonadotropin (hCG)																
	Kovalev			Day A T		Ch!	•												
88	Kovalev Isoform	Meas	ured I	•	nometric Assay For	Isoforms Measured By An Immunometric Assay For Choriocarcinoma-like hCG", J.Endocrinol. 161: 99-106;													
	Kovalev Isoform J.Endoc	Meas	ured F 61: 99	9-106;															
	Kovalev Isoform J.Endoc Spencer	Measinol. 1	ured I 61: 99 (1996	9-106;) "Urine Free	e beta-hCG and Beta														
	Isoform J.Endoc Spencer	s Measinol. 1 et al., (ured I 61: 99 (1996	9-106;) "Urine Free	beta-hCG and Beta	Core in P													

*EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609: Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

·	•								_ (NOV 1 4 2000	EICE		Shee	1 <u>3</u> of <u>1</u> 0	<u>)</u>		
Form PT	O-144	19				U.S Pat	S. D	epartment t and Trade	of (MOV 1 1 2000 Commerce ork Office EMPS	3	Atty. Doci 54205A- JPW/SH	Serial				
	INFO							LOSURE C		ATION		Applicants John O'Connor et al.					
·										333,333		Filing Date August		Group 1641			
								U.S. PAT	EN	T DOCUME	NTS	S					
Examiner Initial		Do	cum	ent i	Num	ber		Date		Name	(Filing Date if Appropriate		
		\bot									_						
		-	_		Ш						_						
		╁									\perp						
	_		ļ														
		ļ_															
		<u> </u>	<u> </u>						_								
		1_	igspace														
		<u> </u>	ļ							· ···							
									<u></u>	-							
							F	OREIGN P	AT	ENT DOCUM	ME	NTS					
	I)ocı	ıme	nt :	Nui	mb	er	Date		Country		Class	Subclass	Tran	slation		
														Yes	No		
			OTI	HER	R DC	OCU	J M I	ENTS (Includ	ing .	Author, Title, Da	ate, l	Pertinent	Pages, Etc.)				
.	Sı	enc	er e	t al	., (1	199	3) '	'Stability of	Inta	act Chorionic (Gon	adotropi	n (hCG) in Sert	ım,			
88							-				•		s: Impact on Scr a <u>.Chem.</u> 39: 106	_			
88	Sı	enc	er e	t al	., (1	199	7) '	Biochemica	al M	larkers of Trisc	omy	21 in A	mniotic Fluid",	Prenat.	Diagn.		
	17	7: 31	-37	'. •													
8%	V	aler	io e	t al.	, (1	996	5) "	Maternal Se	run	Screening of	Fet	al Chron	nosomal Abnor	nalities	by		
χ,	A	FP,	UE:	3, h	CG	an	d fi	ree-βhCG",	Mir	nerva.Ginecol.	48:	169-173	3;				
*	W	ald	et a	1.,(199	4) "	Fo	ur-Marker S	eru	m Screening F	or I	Down's S	Syndrome", Pres	nat.Diag	<u>n.</u>		

*EVAMINED: Initial if citation considered, whether or not citation is in conformance with MPEP 609: Draw line the

*EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609: Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

DATE CONSIDERED

·	_						_				She	et <u>4</u> of	10		
Form P	ГО-1	449)			•	U.S. I Paten	Departmen t and Trac	nt of Commertee of Commerk Office	Atty. Doci	PCT-US 🏋	Seria 0076	WEB		
	INI	FOI	RM (U	AT se s	IO eve	N I	DISCI shee	LOSURE (7000	JPW/SHS/MVM Applicants John O'Connor et al.					
				_					MADEMAR	Filing Date August 1, 2000 TECH COMMISSION 1641					
								U.S. PA	TENT DOCUMENT	S					
Examiner Initial			Doc	ume	ent N	lum	ber	Date	Name	Class	Subclass	Filing Date if Appropriate			
		Ш		_											
						_									
					\perp					ļ					
					\neg										
		l	LI				F	OREIGN	PATENT DOCUME	NTS					
		D	ocu	me	nt l	Vui	mber	Date	Country	Class	Subclass	Tra	nslation		
												Yes	No		
												1 1			
		\vdash					_	 							
		Н		\dashv			 					1			
				ти	ED.	 DO	CHMI	ENTS (Inclu	l ding Author, Title, Date,	Partinent	Pages Ftc)				
		Wa							ter Biochemical Scree			me" <i>f</i>	nn Med		
		<u> </u>	23			1,,,	1) 1		- Diodionina Scient	101 1	<i>50</i>				
		_					ol (1	006) "A ga	-Independent Indices	in Second	Trimester Ser	um Sc	reening		
		⊢					`				-Timester Ser	<u> </u>	recining		
		-				-			ess", Prenat.Diagn. 16:				44		
		-							of Nicked Human Ch						
			-					ragment Frogy 133: 13	rom Standard Referen	ce Prepar	ations and Raw	Urine	;		
		-							· · · · · · · · · · · · · · · · · · ·	Multiple	Urinary Forms	· Mol	Cell		
		_							n of hCG and hLH to		Offilary Forms	, <u>IVIOI</u> .	CEII		
	<u></u>						: 121-		CIDEDED	*****					
EXAMIN	er Ser	R.		D	h	Y		DATE CON	SIDERED						

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609: Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Sheet 5 of 10 U.S. Department of Commerce Form PTO-1449 Atty. Docket No. Patent and Trademark Office 54205A-PCT-US JPW/SHS/MVM INFORMATION DISCLOSURE CITATION Applicants MOV 1 4 2000 (Use several sheets if necessary) John O'Connor et al. TEOR CENTER 1600/2000 Filing Date August 1, 2000 1641 U.S. PATENT DOCUMENTS **Document Number** Date Name Class Subclass Filing Date if Appropriate FOREIGN PATENT DOCUMENTS **Country** Class **Subclass** Translation **Document Number** Date Yes No OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

α	Birken et al., (1996) "Isolation and Characterization of Human Pituitary Chorionic
84	 Gonadotropin", Endocrinology 137: 1402-1411;
$\alpha l l$	Cole et al., (1993) "The Deactivation of hCG by Nicking and Dissociation",
82	J.Clin.Endocrinol.Metab. 76: 704-710;
d	Cole et al., (1985) "The Structures of the Serine-linked Sugar Chains on Human Chorionic
80	Gonadotropin", Biochem.Biophys.Res.Commun. 126: 333-339;
88	Ellish et al., (1996) "A Prospective Study of Early Pregnancy Loss", Hum.Reprod.
88	11: 406-412:

EXAMINER

Examiner

Initial

DATE CONSIDERED

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609: Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Sheet 6 of 10 Form PTO-1449 **U.S. Department of Commerce** Atty. Docket No. Serial No. Patent and Trademark Office **54205A-PCT-US** 09/630,215 JPW/SHS/MVM INFORMATION DISCLOSURE CITATION Applicants (Use several sheets if necessary) John O'Connor et al. Filing Date August 1, 2000 1641 U.S. PATENT DOCUMENTS Examiner **Document Number** Date Name Class Subclass Filing Date Initial if Appropriate FOREIGN PATENT DOCUMENTS **Document Number** Date Country Class Subclass Translation Yes No OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.) Hoermann et al., (1994) "Immunological Recognition and Clinical Significance of Nicked Human Chorionic Gonadotropin in Testicular Cancer", Clin.Chem. 40: 2306-2312; Kovalevskaya et al., (1995) "HLH Beta Core Fragment Immunoreactivity in the Urine of Ovulating Women: A Sensitive and Specific Immunometric Assay for its Detection", Endocrine 3: 881-887; O'Connor et al., (1994) "Recent Advances in the Chemistry and Immunochemistry of Human Chorionic Gonadotropin: Impact on Clinical Measurements", Endocr.Rev. 15: 650-

O'Connor et al., (1998) "Differential Urinary Gonadotropin Profiles in Early Pregnancy and Early Pregnancy Loss", Prenat.Diagn. 18: 1232-1240;

XAMINER DATE CONSIDERED

683;

*EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609: Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

rorm P			1 A T	ıo.	Pat	en	t and Trad	lemark Office	54205A JPW/SH	09/6	09/630.215		
	INT	J)	Jse s	eve	ral sh	eet	ts if necess	ary , NOV 1 1 2000	John O	Connor et al.	Groi	7 2005	
								FENT DOCUMENT	August	1, 2000	164	<u> </u>	
		_		· · · · · · · · · · · · · · · · · · ·			U.S. PAT	FENT DOCUMENT	S	-	CAN UE	iien issa	
Examiner Initial	.	Do	cume	ent N	umber		Date	Name	Class	Subclass	Filing Date if Appropriate		
						+							
		-			+								
				+									
		 											
				\top		•							
					•	F	OREIGN	PATENT DOCUME	NTS		<u>.</u>		
		Doci	ıme	nt N	lumb	er	Date	Country	Class	Subclass	Tra	nslation	
											Yes	No	
:		<u> </u>							<u> </u>		<u> </u>		
			ОТН	ER	DOCL	MI	ENTS (Inclu	ding Author, Title, Date	, Pertinent	Pages, Etc.)			
		'Co	nnor	et a	al., (19	988	3) "Develop	ment of Highly Sensi	itive Imm	unoassays to M	easur	e Human	
88								-subunit, and Beta Co 3: 1361-1366;	ore Fragn	nent in the Urine	: Apj	plication	
98	V	/ilco	x et	al.,	(1988	3) "	Incidence of	of Early Loss of Pregr	nancy", <u>N</u>	.Engl.J.Med. 31	9: 18	9-194;	
0,	·												
1		inan	nan e	et al	., (199	96)	"Estimates	s of Human Fertility a	nd Pregn	ancy Loss", Fer	til.Ste	eril.	
	6.	5: 50)3-5	09;									
88	Α	ceve	edo e	et al	., (199	92)	"Expression	on of Membrane-asso	ciated Hu	man Chorionic	Gona	dotropin,	
	It	s Su	buni	its, a	and Fi	ag	ments by C	Cultured Human Canc	er Cells",	Cancer 69(7): 1	829-	1842;	
EXAMINI	ER	B.	K	3-	al	1	DATE CON	SIDERED					
								on is in conformance with MI next communication to application		w line through citation	n if not	in	

										Sne	et <u>8</u> of	10			
Form PT	O-144	19			U.S Pat	S. D	epartmen and Trac	cit of Commerce demark Office Cit ATION ary	Atty. Doci 54205A JPW/SI	ket No. -PCT-US IS/MVM		30,215			
	INFO			ON vera	DIS	CL eet	OSURE (s if necess	CITATION and the ary) was 1	Applicant John O'	s Connor et al.	FE	CEIVE			
								THE CHART	Filing Dat August	e	Group 7. 7 20				
							U.S. PA	TENT DOCUMENT	ГS		TECH CENTER 160				
xaminer nitial		Doo	ument	Nur	nber		Date	Name	Class	Subclass	Filing Date if Appropriate				
		+		_	-		-								
		-		+											
		-		+	-						-				
	-	-	-	+											
			$\vdash\vdash$		1										
				┿	 						 				
		+		+-											
	<u> </u>	1	LI	<u> </u>		<u>. </u>				<u> </u>					
								PATENT DOCUM	T		T				
	1	Jocu	ıment	INU	mb	er	Date	Country	Class	Subclass		<u>nslation</u>			
		T		1	1					-	Yes	No			
		+		+-							+	-			
		+		+							+				
		-		1	\vdash						+				
			THE	D DO	CU	ME	NTS (Includ	l ding Author, Title, Date	Pertinent	Pages Ftc)					
, [В						•	Human Chorionic G			nt Wo	men			
50	ar	ıd Tı	umor	Pati	ents	Re		by Monoclonal Antib							
4/								nt and Characterizati	on of Cho	orionic Gonado	tropin	in			
88		erum	and	Urin	ne fr	om	Patients w	vith Trophoblastic Tu	mors", <u>Cl</u>	inical Investiga	tion 7	1: 953-			
41	C	Cole et al., (1991) "The Heterogeneity of Human Chorionic Gonadotropin (hCG). III.													
88							iological a 1559-156	nd Immunological A 7;	ctivities o	f Nicked hCG",					
1	Н	oern	nann e	et al	., (1	993	Molecu	lar Heterogeneity of	Human Cl	horionic Gonad	otropi	n in			
88		erum 60;	and	Urir	ne fr	om	Patients w	vith Trophoblastic Tu	imors", <u>Cl</u>	inical Investiga	tion 7	1: 953-			
MINE			,	1	,	1	DATE CON	SIDERĘD,							

*EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609: Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Form PT()-144	9					ot of Commerce demark Office CUTATION	•	ket No. -PCT-US HS/MVM	Serial 09/6	1No. 130,215	
]	NFO					LOSURE (ets if necess	CIPATION AND SA	Applicant John O	s Connor et al.		CVIII	
							Reference to the second	August		Cicit 1641	PENTER 160	
						U.S. PA	TENT DÖCÜMENT	CS				
Examiner Initial		Doc	umei	nt Nur	nber	Date	Name	Class	Subclass	Filing if App	Date propriate	
	+	+ -	\vdash	+-	++	 		1		 		
	+	╁┼	\vdash	+	++					-	:	
	+	+	\vdash	-	++-					+		
	+			+	+	+						
		\vdash	$\vdash \vdash$	+	++	 	-	+		+		
	+	╂╌┦	\vdash	-	++	+		<u> </u>		 		
	+	┼┤	\vdash		+	 			ļ	+		
	-	╀╌┤		+	++	 	<u> </u>			+-		
		Ш	Ш			COPPICAL	T : TENTE DOCUME	23.770	<u> </u>	<u> </u>		
				. N.T		1	PATENT DOCUME	1				
	1	Document Number Date Country Class Subclass Trans										
	+	 			Т	+ + +		-	Yes	No		
	+	-	$\vdash \vdash$	+	++	-	-	<u> </u>	 			
		\dashv	\vdash	+	++					+		
	-	\sqcup	$\vdash \vdash$	+	++			<u> </u>		++		
		للـــــــــــــــــــــــــــــــــــــ	Щ									
 			-				ding Author, Title, Date			-i C		
Q4							luation of Nicked Hu					
							fic Immunometric As		<u> </u>			
04				<u>`</u>		-	of Nicked Human Ch	· · · · · · · · · · · · · · · · · · ·				
				•	_	ment from (): 1390-139	Standard Reference P	reparation	is and Raw Urin	e Samj	pies",	
41							ve Study of Early Pres	gnancy La	oss". Human Rei	 produc	tion	
88				7-408;		TTTOSPECT	ve Study of Dairy 110,	gnare y 13	oos , <u>raditali re</u> j	produc		
	-	<u> </u>				4) "Immun	ological Recognition	and Clini	cal Significance	of Nic	ked	
88							in Testicular Cancer"					
EXAMINER			<u>, , , , , , , , , , , , , , , , , , , </u>	Br	het	DATE CON		Omnour	Chemony 10(12	<u>.). 230</u>		
			ation 4	conside	red whe	ther or not citat	ion is in conformance with MI	PEP 609: Dra	w line through citation	if not in		
							next communication to applica					

Form PT					Pate	nt and Trac	t of Commerce demark Office PECITATION	Atty. Docket No. 54205A-PCT-US JPW/SHS/MVM							
	INFO						LOSURE (ets if necess	/ 190	Applicants John O'Connor et al.						
								TENT DOCUMENT	Filing Dat August		Group GNESS GENESS	600/2900			
							U.S. PA	TENT DOCUMENT	S						
Examiner Initial		Doc	ume	ent î	Num	ber	Date	Name	Class	Subclass		Filing Date if Appropriate			
		-													
						+						-			
<u> </u>			<u>l</u>				FOREIGN	PATENT DOCUME	ENTS						
	D	ocu	ıme	nt	Nu	mbei	Date	Date Country	Class	Subclass		slation			
		1	I			~					Yes	No			
											-				
		1													
4.1								ding Author, Title, Date,							
88	Kı	nigh	t, (1	198	9) '	'The	Carbohydra	te Frontier", Biotechn	ology 7(1): 35 and 39-40	<u>, </u>				
	— ₀ ,	Cor	າກດາ	r et	al	(198	(8) "Develo	pment of Highly Sens	itive Imn	nunoassavs to M	easure				
88	Hı	uma	n C	hor	rion	ic Go	onadotropin	, Its β-subunit, and Co				on to			
	- IVI	ang	nan	cie	S ,	Canc	er Keseaich	38: 1361-1366;							
:															
							_ <u>,</u>								
EXAMINE	Eine	C.	§	8	لم	he	DATE CON	SIDERED 5/1/12				_			
*EXAMINEI	R: Initial	if cit	ation lered	con:	sider lude	ed, wh	ether or not citat f this form with	ion is in conformance with MI next communication to application	PEP 609: Dra ant.	w line through citation	if not in				